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DHEC Health Advisory

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Rhodococcus equi Bloodstream Infections Potentially Associated with Contaminated Calcium Gluconate Products Compounded for Infusion

Summary

The Texas Department of Health and Human Services, the Food and Drug Administration, and the Centers for Disease Control and Prevention are investigating a cluster of *Rhodococcus equi* infections potentially associated with contaminated calcium gluconate infusions produced by Specialty Compounding, Cedar Park, TX.

FDA has received reports of 15 adverse events experienced by patients in two hospitals. The 15 patients received an infusion of calcium gluconate 2 grams in Sodium Chloride 0.9% for Injection, which was supplied by Specialty Compounding. The patients then developed bacterial bloodstream infections caused by *Rhodococcus equi*. These infections are thought to be related to the infusions. Cultures from an intact sample of calcium gluconate compounded by Specialty Compounding showed growth of bacteria that are consistent with *Rhodococcus species*.

Recall

Specialty Compounding, LLC has announced a voluntary nationwide recall of all lots of unexpired sterile products. The recall applies to all unexpired sterile compounded products dispensed since May 9, 2013, including all strengths and dosage forms.

Recalled products were distributed directly to hospitals and physician offices in Texas. Recalled products were also sent directly to patients located nationwide with the exception of North Carolina. Specialty Compounding is notifying its customers by telephone, fax, electronic mail, and/or regular mail of this recall.

Guidance for Clinicians

FDA is alerting health care professionals not to use any sterile products supplied by Specialty Compounding, Cedar Park, TX.

Users or recipients of these products should immediately discontinue use and return the recalled unexpired products to Specialty Compounding.

Reporting of Cases

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm[2]
- Download form[3] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-01

Resources for additional information:

1. Specialty Compounding Sterile Products: FDA Alert - Bacterial Infections: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm364595.htm
2. Specialty Compounding, LLC Issues Nationwide Voluntary Recall of All Lots of Unexpired Sterile Products Due to Reports of Adverse Events: http://www.fda.gov/Safety/Recalls/ucm364643.htm

DHEC contact information for reportable diseases and reporting requirements

Reporting of unusual clusters of illness is consistent with South Carolina law requiring the reporting of diseases and conditions to your state or local public health department (State Law # 44-29-10 and Regulation # 61-20). The DHEC 2013 List of Reportable Conditions is available at http://www.scdhec.gov/health/disease/reportables.htm

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease (HIPAA 45 CFR §164.512).

Regional Public Health Offices - 2013

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DHEC Bureau of Disease Control, Division of Acute Disease Epidemiology
1751 Calhoun Street
Columbia SC 29201
Phone: (803) 898-0861
Fax: (803) 898-0897
Nights/Weekends: 1-888-847-0902

Categories of Health Alert messages:

Health Alert	Conveys the highest level of importance; warrants immediate action or attention.
Health Advisory	Provides important information for a specific incident or situation; may not require immediate action.
Health Update	Provides updated information regarding an incident or situation; unlikely to require immediate action.